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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,775	06/23/2000	Neil R. Cashman	50111/002002	9735

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BOSTON, MA 02110

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

17

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,775

Applicant(s)

CASHMAN ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 18-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,7,16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicant's election without traverse of Group I (claims 1-17 and 80) in Paper No. 15 is acknowledged. Claims 18-79 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claims are directed to antibodies that recognize the infectious form of mammalian prion protein, the title should reflect the claimed invention. Correction is requested.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper Nos. 6, 7 and 16, are attached to the instant Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claims 2 and 11, the phrase "does not substantially bind PrP^C" renders the claims indefinite because the specification does not provide a some standard of measuring the degree intended by the phrase "does not substantially bind PrP^C", thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(f).

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-17 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Korth et al. (Nature, 1997, IDS Paper No. 7).

The claims are directed to antibodies that bind with high binding affinity to a YYX epitope. The claims are directed to antibodies that bind the infectious form of the prion protein

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and hybridoma cell line for the production of a monoclonal antibody that recognizes the YYX epitope. Because the limitation (claims 2 and 11) "does not substantially bind" is not defined in such as way in the specification to allow the ordinary artisan to determine at what point an antibody will fall inside or outside the scope the claim, antibodies that can bind both infectious as well as normal prion protein are encompassed by the claim.

For this office action, claim 80 is interpreted as "a composition of matter", Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

Korth et al. disclose monoclonal antibodies 15B3 and 6H4 that recognize a YYX epitope (see figure 2), the reference discloses hybridoma cell lines for the production of the antibodies. The 15B3 antibody binds selectively to the PrP^{Sc} from various species without the need to digest the sample with proteinase K (see page 77, last paragraph). The reference discloses immunoprecipitation experiments (see figure 1 and 2; page 77 characterization of antibodies) and the compositions required for carrying out these experiments. Kits are merely a packaging of the components to carry out a particular experiment. In the reference 0/0 mice were injected with prion protein in which a YYR epitope is located on the outside of the molecule (see figure 3) therefore the antibodies generated by the mouse are polyclonal antibodies against a YYX epitope. The office does not have laboratory facilities to test whether the antibodies of the prior

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art which bind a YYX epitope will also bind the YYX epitope found in SEQ ID NO: 32 or 33.

Barring any evidence to the contrary the presumption is that the prior art antibodies bind these epitopes as well. Therefore, the instant invention is anticipated by Korth et al.

Claims 1-17 and 80 are rejected under 35 U.S.C. 102(a) as being anticipated by Korth et al. (WO 98/37210, see IDS) or under 35 U.S.C. 102(b) by Korth et al. (EP 0 861 900, see IDS)

The claims are directed to antibodies that bind the infectious form of the prion protein, specifically the YYX epitope, and hybridoma cell line for the production of a monoclonal antibody that recognizes the YYX epitope. Because the limitation (claims 2 and 11) "does not substantially bind" is not defined in such a way in the specification to allow the ordinary artisan to determine at what point an antibody will fall inside or outside the scope the claim, antibodies that can bind both infectious as well as normal prion protein are encompassed by the claim.

For this office action, claim 80 is interpreted as "a composition of matter", Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

Korth et al. disclose monoclonal antibodies 15B3 and 6H4 that recognize a YYX epitope, the reference discloses hybridoma cell lines for the production of the antibodies (see claim 1, 2, 8, 10). The 15B3 antibody binds selectively to the PrP^{Sc} from various species without the need

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to digest the sample with proteinase K . The reference discloses immunoprecipitation experiments (see claim 25) and the compositions required for carrying out these experiments as well as kits. In the reference 0/0 mice were injected with prion protein in which the YYR epitope is located on the outside of the molecule (see claim 22) therefore the antibodies generated by the mouse are polyclonal antibodies against a YYR epitope. The office does not have laboratory facilities to test whether the antibodies of the prior art which bind a YYX epitope will also bind the YYX epitope found in SEQ ID NO: 32 or 33. Barring any evidence to the contrary the presumption is that the prior art antibodies bind these epitopes as well. The reference also discloses using the antibody as therapeutic agents (see WO 98/37210 page 22). Therefore, the instant invention is anticipated by Korth et al.

Conclusion

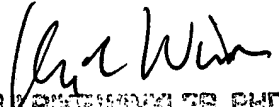
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D. 4/7/03
PATENT EXAMINER